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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,447	04/13/2004	Scott Phillip Baron	PC20557A	4965

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WARNER-LAMBERT COMPANY
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EXAMINER	
CHEN, SHIN LIN	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/823,447	BARON ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-40 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, drawn to a genetically-modified non-human mammal comprising an alpha2/delta1 gene comprising an R217-like mutation, wherein the modification results in a mutated alpha2/delta1 gene encoding a polypeptide selected form the groups as recited in claims 2, 3 and 5, classified in classes 800, subclasses 14 and 18, respectively.

II. Claims 10-13, drawn to an isolated nucleic acid molecule having a sequence encoding a polypeptide comprising the sequence of SEQ ID No. 17, 18 or 19, or a nucleic acid sequence comprising SEQ ID No. 20, 21, 22, 23, or 24, classified in class 536, subclass 23.5.

III. Claim 14, drawn to a genetically-modified non-human mammal comprising the nucleic acid of claim 10, classified in class 800, subclasses 14.

IV. Claims 17-23, drawn to genetically modified animal cell comprising a mutated gene encoding a polypeptide of claim 2, classified in class 424, subclass 93.21.

V. Claims 24 and 25, drawn to a method of identifying a gene that demonstrates modified expression as a result of reduced alpha2/delta1 activity in an animal cell, classified in class 435, subclass 6.

VI. Claims 26 and 27, drawn to a method of identifying a protein that demonstrates modified expression or post-translation modification as a result of reduced alpha2/delta1 activity in an animal cell, classified in class 435, subclass 7.1.

VII. Claims 15, 16, 28 and 29, drawn to a targeting vector for producing a transgenic animal, a host cell comprising said vector, and a method of producing a transgenic

animal by using a targeting vector, classified in classes 435 and 800, subclasses 320.1 and 25, respectively.

VIII. Claims 30-33, drawn to a method for determining whether the physiological effect of a compound on a disorder or activity involves alpha2/delta1 subunit polypeptide residues mediating the effect of an alpha2/delta1 ligand by using the mammals of claim 2, classified in 435, subclass 4.

IX. Claim 34, drawn to a method for identifying compounds that exert their physiological effect on a disorder or activity through an alpha2/delta1 subunit polypeptide by treating mammals of claim 2 and wild-type mammals with a test compound and compare the response, classified in class 800, subclass 3.

X. Claim 35-37, drawn to a method for identifying compounds that exert their physiological effect on a disorder or activity through an alpha2/delta1 subunit polypeptide by treating mammals of claim 2 with a ligand that binds an alpha2/delta1 subunit polypeptide and treating the wild-type mammals with a test compound and compare the response, classified in class 800, subclass 3.

XI. Claims 38-40, drawn to a method for determining a role of alpha2/delta1 polypeptide in an activity or disorder comprising subjecting the mammals of claim 2 and wild-type mammals to a procedure indicative of an activity or disorder and comparing the response, classified in class 800, subclass 3.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are patentably distinct from each other because they are drawn to compositions having different chemical structures, physical properties, and biological functions:

genetically-modified non-human mammal vs. nucleic acid molecules. Further, the nucleic acid sequence involved in the genetically-modified non-human mammal is SEQ ID No. 25, 26, 27, 28, 29, 30, or 31 but not SEQ ID Nos. 17-24. They have different classifications and require separate search. Thus, groups I and II are patentably distinct from each other.

Groups II and III are patentably distinct from each other because they are drawn to compositions having different chemical structures, physical properties, and biological functions: genetically-modified non-human mammal vs. nucleic acid molecules. They have different classifications and require separate search. Thus, groups II and III are patentably distinct from each other.

Groups I and III are patentably distinct from each other because they are drawn to compositions having different chemical structures, physical properties, and biological functions: genetically-modified non-human mammal comprising the sequence of SEQ ID No. 25, 26, 27, 28, 29, 30, or 31 vs. genetically-modified non-human mammal comprising the sequence of SEQ ID No. 17, 18, 19, 20, 21, 22, 23, or 24. They are different mammals having different genotypes and phenotypes, and require separate search. Thus, groups I and III are patentably distinct from each other.

Groups I, III and group IV are patentably distinct from each other because they are drawn to compositions having different chemical structures, physical properties, and biological functions: genetically-modified non-human mammal vs. cells. Further, the nucleic acid sequence involved in the genetically-modified non-human mammal group III is SEQ ID Nos. 17-24 but not SEQ ID No. 25-31. They have different classifications and require separate search. Thus, groups I, III and group IV are patentably distinct from each other.

Groups II and IV are patentably distinct from each other because they are drawn to compositions having different chemical structures, physical properties, and biological functions: nucleic acid sequence vs genetically-modified animal cells. Further, the nucleic acid sequence involved in the genetically-modified animal cell of group IV is SEQ ID Nos. 25-31 but not SEQ ID No. 17-24 of group II. They have different classifications and require separate search. Thus, groups II and IV are patentably distinct from each other.

Groups V-XI are distinct from each other because they are drawn to materially different methods that differ at least in objectives, method steps, reagents used, dosages and schedules used, response variables, and criteria of success. They have different classifications and require separate searches. Thus, groups V-XI are not obvious variants and are patentably distinct from each other. Similarly, groups III, V and VII are patentably distinct from each other for the same reason.

Group I is unrelated to groups V-VI because the product of group I is not involved or otherwise used in the process of groups V-VI. Thus, group I is patentably distinct from groups V-VI.

Groups II-IV are unrelated to groups V-XI because the product of groups II-IV is not involved or otherwise used in the process of groups V-XI. Thus, groups II-IV are patentably distinct from groups V-XI.

Inventions I and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the

genetically-modified non-human mammals can be made by microinjecting the DNA sequence into pronucleii instead of using homologous recombination in ES cells. Thus, inventions I and VII are patentably distinct from each other.

Invention I and inventions VIII-XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the genetically-modified non-human mammals can be used to produce a recombinant protein instead of being used to identify compounds or determine a role of alpha2/delta1 polypeptide. Thus, invention I and inventions VIII-XI are patentably distinct from each other.

Upon election of groups I, IV and VII-XI, further restriction is required. Since SEQ ID Nos. 25-31 represent different nucleotide sequence encoding distinct polypeptides having different biological functions and the mutations recited in claims 2, 3 and 5 represent different mutations, therefore, the genetically-modified non-human mammals would have distinct genotype and phenotypes and they differ physiologically and pathologically. Applicants are required to elect a **single** SEQ ID No. from SEQ ID Nos. 25-31 or one mutation, and corresponding phenotype(s) for examination. It should be noted that this is a restriction requirement rather than an election of species.

Upon election of groups II and III, further restriction is required. Since SEQ ID Nos. 17-24 represent different nucleotide sequence encoding distinct polypeptides having different

biological functions and the genetically-modified non-human mammals would have distinct genotype and phenotypes and they differ physiologically and pathologically. Applicants are required to elect a **single** SEQ ID No. from SEQ ID Nos. 17-24 for examination. It should be noted that this is a restriction requirement rather than an election of species.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.

SHIN-LIN CHEN
PRIMARY EXAMINER